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**UNITED STATES DEPARTMENT OF COMMERCE**  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/717,294	09/20/96	SEED	B 00786/345001

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NM12/0129

EXAMINER

DEGEN, N

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 01/29/99

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/717,294

Applicant(s)

Seed et al.

Examiner

Nancy J. Degen

Group Art Unit

1636



☒ Responsive to communication(s) filed on Nov 18, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-10, 17-20, and 25-28 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-10, 17-20, and 25-28 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 15

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit:

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-10, 17-19 and 25-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Seed et al. (World Patent Application No. 96/09378).

Seed discloses synthetic genes encoding mammalian proteins that are expressed at a higher level than native genes. The synthetic genes have non-preferred codons replaced by preferred codons. Proteins such as Factor VIII may have their expression level increased by replacing codons. Expression levels can be increased by as much as 10,000%. From 10%-90% of the codons in the natural protein are non-preferred and/or are replaced. Vectors containing the synthetic gene and mammalian cells harboring the vector are also disclosed (Seed, page 1, line 20 through page 4, line 26). Seed also teaches that in a preferred embodiment the CG sequence is highly underrepresented (Seed, page 17, lines 27-39 and page 25, line 22 through page 26, line 34). Seed discloses each and every aspect of the instant invention, thereby anticipating Applicants' claimed invention.

3. Claims 1-10, 17-19 and 35-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Seed et al. (U. S. Patent No. 5,786,464).

Art Unit:

Seed discloses synthetic genes encoding mammalian proteins that are expressed at a higher level than native genes. The synthetic genes have non-preferred codons replaced by preferred codons. Proteins such as Factor VIII may have their expression level increased by replacing codons. Expression levels can be increased by as much as 10,000%. From 10%-90% of the codons in the natural protein are non-preferred and/or are replaced. Vectors containing the synthetic gene and mammalian cells harboring the vector are also disclosed (Seed, col. 1, line 29 through col. 2, line 63). Seed also teaches that in a preferred embodiment the CG sequence is highly underrepresented (Seed, col. 10, line 58 through col. 11, line 3 and col. 14, line 57 through col. 15, line 33). Seed discloses each and every aspect of the instant invention, thereby anticipating Applicants' claimed invention.

***Response to Amendment***

4. The rejections set forth in the previous action are maintained. Applicants are in the process of changing the inventorship of the U. S. Patent and the World Patent Application which will render these rejections moot. At the time of approval of the change in inventorship, these rejections will be withdrawn.

Art Unit:

5. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Nancy J. Degen, whose telephone number is (703) 308-3672. The Examiner can normally be reached on Monday-Thursday from 8:00 AM-5:30 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, George Elliott, can be reached at (703) 308-4003. The fax phone number for this Group is (703) 305,7939.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

NJD  
January 28, 1999



**NANCY DEGEN  
PRIMARY EXAMINER**